REMARKS

Obviousness Rejection

Claims 1-13 were rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 6,495,177 ("de Vries") in view of U.S. Pat. 5,380,541 (Beyts"). (Office Action at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

De Vries discloses

(57) **ABSTRACT**

The present invention provides an orally administrable nutritional supplement which is highly palatable, such as a chewable prenatal vitamin/mineral supplement. The supplement is preferably made in the form of a tablet that, upon chewing, dissolves rapidly in the mouth. The tablet is particularly suitable for administration of vitamins and minerals to women during pregnancy. The invention also includes methods of making and using such supplements.

SUMMARY OF THE INVENTION

The invention relates to a highly palatable, prenatal nutritional supplement in a chewable form which comprises a prenatally relevant amount of at least one vitamin or mineral and an alkyl polysiloxane. Preferably, the supplement is a chewable tablet. The invention includes supplements which include folic acid, an iron compound, or both of these, as well as those which also include other vitamins or minerals. By way of example, a folic acid-containing supplement can be made for administration to women who are pregnant or who anticipate becoming pregnant. In one embodiment, the

(Col. 3)

The highly palatable nature of the supplement provided herein lends itself to preparation of various unit dosage forms, such as chewable tablets and orally administrable powders and granulated preparations. In one aspect of the invention, the unit dosage form is a chewable tablet which comprises

(a) about 0.1–2.0 milligrams of folic acid, or a pharmaceutically acceptable salt form thereof (preferably at least about 1.0 milligram; e.g. about 1.25 milligrams);

(b) about 100–800 International Units (I.U.) of vitamin D_3 (preferably at least about 400 I.U.; e.g. about 440 I.U.);

(c) about 100–4000 or 100–2000 I.U. of beta carotene (or another pharmaceutically acceptable form of vitamin A, such as vitamin A acetate; preferably the unit dosage form comprises at least about 1000 I.U.; e.g. about 1100 I.U. of vitamin A);

(d) about 0.2–8 milligrams of vitamin B_1 (preferably at least about 2 milligrams; e.g. about 2.4 milligrams);

(e) about 0.5–10 milligrams of vitamin B_2 (preferably at least about 3 milligrams; e.g. about 3.5 milligrams);

(f) about 2–200 or 2–20 milligrams of vitamin B_6 (preferably at least about 10 milligrams; e.g. about 12 milligrams);

(g) about 2–20 micrograms of vitamin B_{12} (preferably at least about 12 milligrams; e.g. about 14.4 milligrams);

(h) about 1–200 or 1–20 I.U. of vitamin E (preferably at least about 11 I.U.; e.g. about 13.2 I.U.);

(i) about 20–200 milligrams of vitamin C in the form of ascorbic acid and/or a pharmaceutically acceptable salt thereof (preferably at least about 120 milligrams; e.g. about 132 milligrams);

(j) about 5–40 milligrams of niacinamide or an equivalent molar amount of niacin (preferably at least about 20 milligrams of niacinamide; e.g. about 22 milligrams);

(k) about 1–100 milligrams of elemental iron in the form of a pharmaceutically acceptable iron compound (preferably at least about 15 milligrams; e.g. about 15, 30, 45, 60, or 90 milligrams).

(Col. 4)

the course of about 24 hours).

The chewable prenatal supplement described herein can comprise a chewable tablet base, such as a base which comprises one of mannitol, sucrose, sorbitol, dextrose, com-

(Col. 4)

pressible cellulose, compressible honey, compressible molasses, compressible sugar, and lactose as a primary ingredient. As described herein, such supplements can be prepared in a form which has an interior that is noticeably softer than its exterior. By way of example, the base can comprise an agglomerate which comprises 90–99% by weight of carbohydrate-based material selected from the group consisting of dextrose, a combination of dextrose monohydrate and maltodextrin, fructose, a combination of fructose and maltodextrin, sucrose, a combination of sucrose and maltodextrin, maltose, a combination of maltose and maltodextrin, mannitol, xylose, and a combination of xylose and maltodextrin; and 10–1% by weight of a water soluble binder selected from the group consisting of maltodextrin, corn syrup solids, dextrose, sucrose, poly(vinylpyrrolidone), and cooked starch paste. In such an agglomerate, the carbohydratebased material can, for example, be selected from the group consisting of dextrose monohydrate, a combination of dextrose monohydrate and maltodextrin, fructose, dextrose, mannitol, a combination of fructose and maltodextrin, sucrose, a combination of sucrose and maltodextrin, maltose, a combination of maltose and maltodextrin, xylose, and a combination of xylose and maltodextrin. The water soluble binder is preferably maltodextrin.

and

US 6,495,

form. Finely divided components also flow well in tablet presses and other processing machinery, and tend to make tablets having advantageous properties (e.g. chip resistance, homogeneity, etc.). Preferably, not less than about 70% of the finely divided ingredients will pass through a 60 mesh (250 micrometer) screen. In another embodiment, not less than about 80%, even more preferably not less than 90%, of a component will pass through a 50 mesh (300 micrometer) screen. In another embodiment, not less than 80%, more preferably not less than 90%, of a component will pass through a 100 mesh (150 microns) screen.

De Vries has an effective filing date of August 13, 1999.

Beyts dlscloses

[57] **ABSTRACT**

Synergy is is obtained by combining sucralose and a sweet saccharide selected from fructose; glucose; maltose and other glucooligosaccharides; fructose mixed with glucose and/or gluco-oligosaccharides; lactose; isomaltulose; and sugar alcohols.

According to the present invention there is provided a sweetening composition for sweetening ingestible compositions and oral products, the composition consisting essentially of sucralose; a sweet saccharide selected from fructose; glucose; maltose and other glucooligosaccharides; glucose mixed with maltose and other oligosaccharides; fructose mixed with glucose and/or gluco-oligosaccharides, lactose, isomaltulose, and sugar alcohols, and, optionally, a carrier for a sweetening composition; the relative sweetness contribution provided by the sucralose and the sweet saccharide being from 5:1 to 1:5. By the term "sweetening composition", we mean a composition for use in sweetening foodstuffs, beverages etc, e.g. sweetening tablets and granules, concentrates for the beverage industry etc.

(Col. 2.)

EXAMPLE 9

Peppermint tablet

	Sorbitol % w/w	Mannitol % w/w	Xylitol % w/w
Sucralose	0.01	0.01	0.005
Sorbitol[1]	98.19	—	—
Mannitol[1]	—	98.19	—
Xylitol[1]	—	—	98.195
Magnesium Stearate[2]	1.00	1.00	1.00
Peppermint Durarome[3] sugar free 386292	0.80	0.80	0.80

1. Roquette (UK) Ltd
2. Crosfield & Gerry Ltd, U.K.
3. Semsons Taylor Ingredients, U.K.

In making the rejection, the Examiner asserted that de Vries

'177 teaches orally dissolvable chewable tablet that is palatable and also dissolves rapidly in the mouth. The tablet of '177 includes active agents in the form of vitamin supplements such as folic acid, beta carotene, vitamin B12 etc, an effective amount alkyl polysiloxane to improve the texture of the supplement and a chewable base comprising a material selected from the group consisting of mannitol, sucrose, sorbitol, dextrose, cellulose derivatives etc (lines bridging col. 4-5). In particular, '177 teach an agglomerate base that comprises 90-99% by weight of carbohydrate-based material selected from dextrose, fructose, sucrose, dextrose monohydrate and maltodextrin or combinations thereof, which meets the limitation of claim 5; and a binder in an amount of 1-10% by weight of the composition (col. 10, lines 50-65). Instant specification does not define the term "substantially free". Further, the specification also states that the binders such as microcrystalline cellulose are less than 20% or even less than 10%. Thus, the amount of binder (1-10% by weight) taught by '177 is within the claimed range. '177 further teaches preparing carbohydrate agglomerate that has a particle size of 20 microns to 100 microns, the upper limit of which overlaps the claimed particle size (100 to 250 microns). For active agent, 177 teaches vitamins, minerals, nutrients and insoluble metal carbonates, oxides etc (col. 10, (Office Action at 2.)

lines 43-49) and teaches preparing the tablets by granulation (col. 11, lines 12-37). '177 teaches that chewable tablets are usually associated with disagreeable or bad taste and a bad mouth feel that is due to the chewy, gritty, oily, creamy or sticky consistency of the tablet and suggests addition of sweeteners such as saccharin, dextrose, sucrose, aspartame, fructose oligosaccharide etc (col. 1 and col. 8, lines 7-15) and states that the carbohydrate material in the agglomerate itself can be a sweetening agent in the composition. However, '177 fail to teach sucralose of instant claims (Office Action at 3.)

The Examiner acknowledged, however, that de Vries differs from the presently claimed invention in that de Vries "fail[s] to teach sucralose of the instant claims." (Office Action at 3.)

To fill the acknowledged gap, the Examiner relied upon Beyts as teaching

'541 teach sucralose containing ingestible compositions such as medicaments, beverages, etc. '541 teaches that a synergy in obtaining sweetness is observed with sucralose and other saccharides such as glucose, fructose, mannitol, sorbitol, or fructose mixed with glucose. Example 1 of '541 shows the synergy of sucralose with various sweeteners such as fructose etc., and the list of sweetener blends with sucralose in col. 5, specifically mentions a combination of dextrose monohydrate and sucralose that reads on the instant claimed components. Further example 9 is directed to a peppermint tablet, which meets the description of a chewable tablet.

The Examiner then concluded that "it would have been obvious for one of ordinary skill in the art at the time of the instant invention to add a synergistic combination of sucralose with other sweeteners such as fructose, dextrose monohydrate, sucrose, glucose, etc.... because [de Vries] desires the present of a sweetener in a chewable tablet composition to avoid unpleasant taste and [Beyts] suggests that sucralose is effective in reducing the caloric level in the final preparation and is much sweeter than the sucrose or other sweeteners." (Office Action at 3.)

Submitted concurrently herewith is a Declaration of Joseph Luber, a joint inventor of the present invention, filed under 37 CFR § 1.131. This Declaration contains a copy of redacted notebook page 101 from Book No. 389 wherein there is described an experiment carried out produced product within the scope of at least claim 1 of the present application. This redacted notebook page was completed on June 30, 1999.

The earliest effective filing of de Vries is August 13, 1999.

Because the Luber Declaration establishes a date of invention of the present invention prior to de Vries earliest effective filing date, the use of de Vries as a reference is improper. Therefore, any rejection based on de Vries must be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,

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